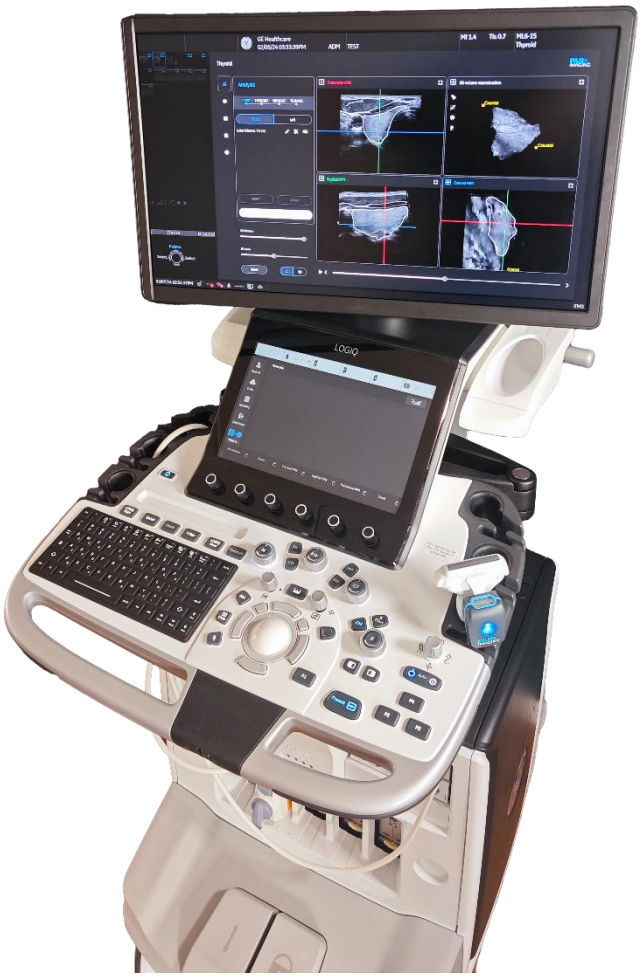
PIUR® tUS inside

User Manual



User Manual

PIUR® tUS inside

Document Revision 15.0

Software version: 1.0.1

Type: PIUR tUS inside

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Table of Contents

1 General Information

1.1 Abbreviations and Terms

Abbreviation / term	Description
US	Ultrasound
tUS	Tomographic ultrasound

1.2 Symbols in User Manual

Symbol	Description
	Helpful **information**, which simplifies daily work with the device.
	**Attention:** Important information that should be understood prior to operating the device.
	**Safety notice.** Situations in which misuse can lead to personal injury or damage to property.

1.3 Symbols on the device

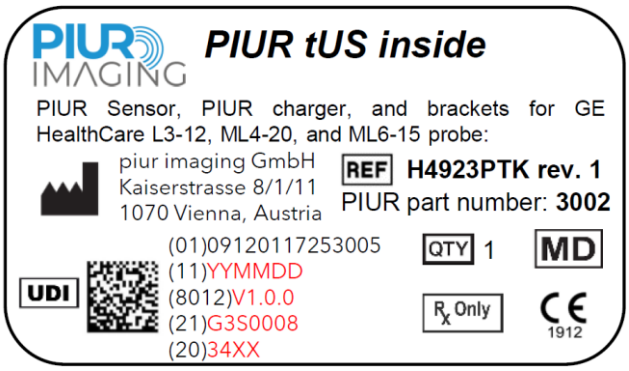
Symbol	Description
	Stand-by symbol
	Charging

1.3.1 Identification Labels

PIUR tUS inside – System Label

The system Label is affixed on Shipping box.

The label with the corresponding software version and UDI parameters (UDI-DI+UDI-PI), can be used to identify the device.

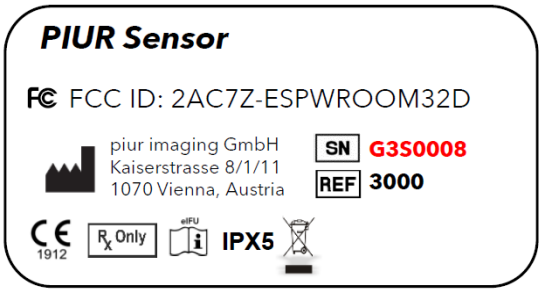


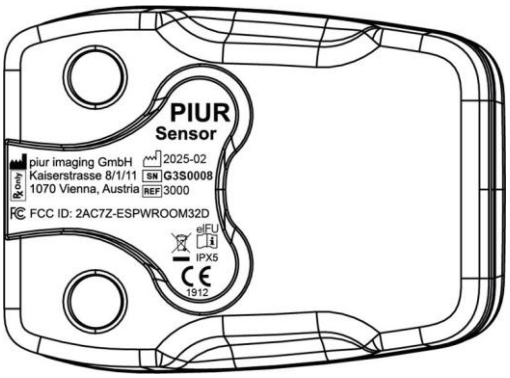
PIUR tUS inside Software

The identification label is displayed in the software itself (software user interface), in plain-text format.

Please note down the software version before contacting the PIUR service.

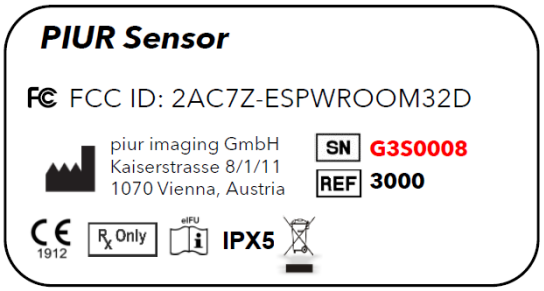
PIUR Sensor

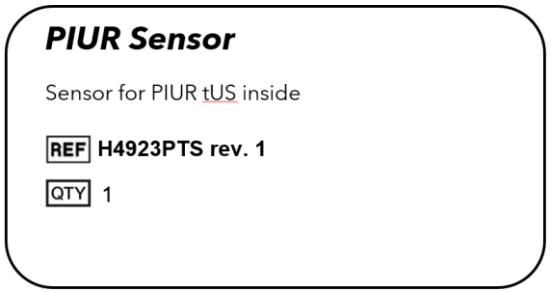




PIUR Sensor Box

Sensor packaging Label is affixed on the PIUR Sensor Box.

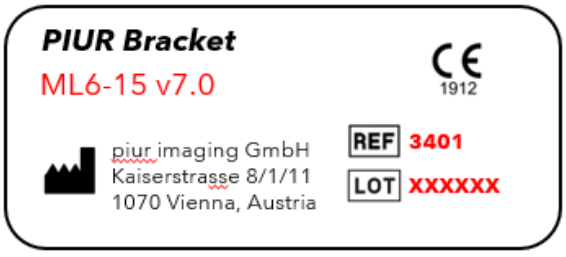


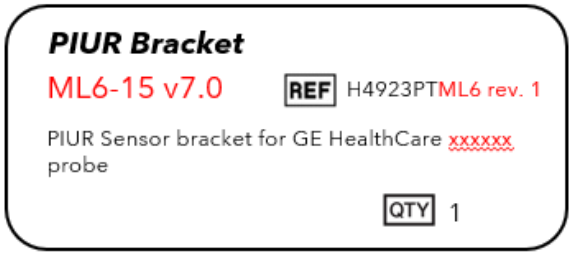


PIUR Bracket

Label specification for PIUR Bracket contains Model type, Version number and REF number (depending and based on the type).

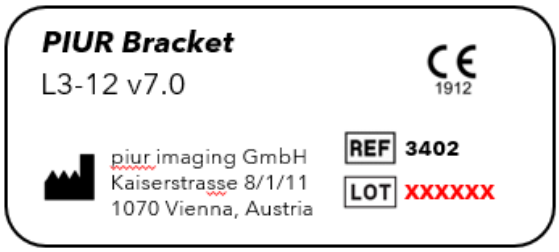
The Label is affixed on the PIUR Bracket packaging box.

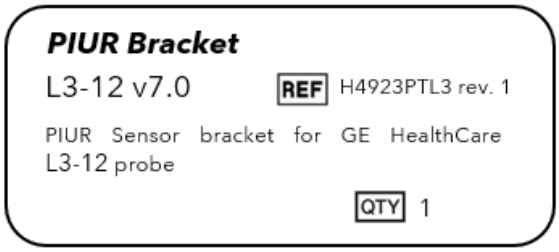




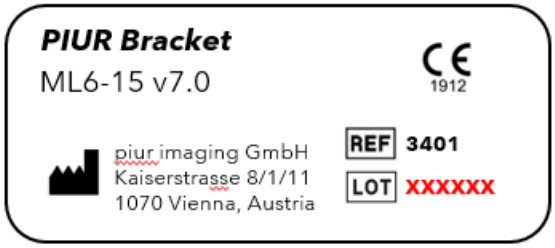
Variants for the three probes:

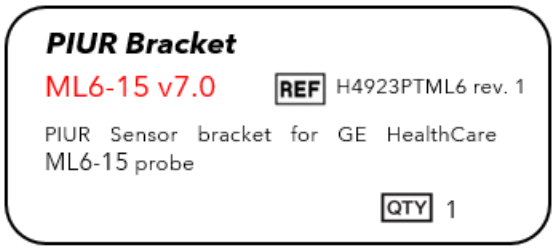
L3-12 Probe



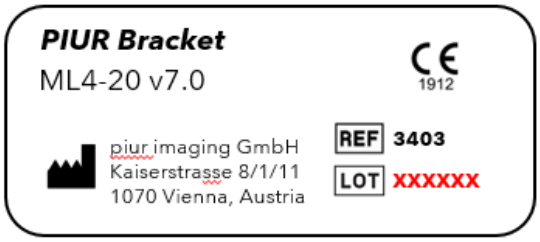


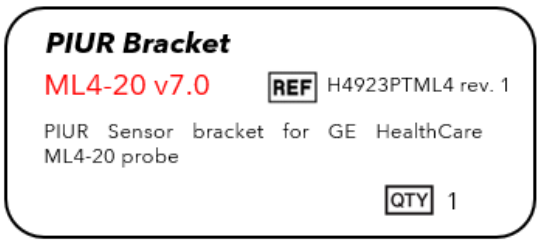
ML6-15 Probe





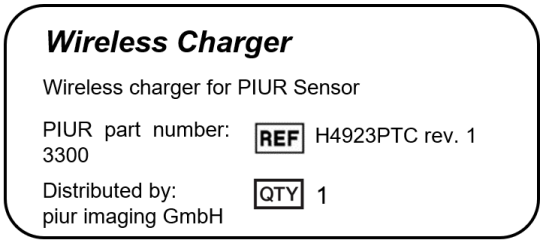
ML4-20 Probe



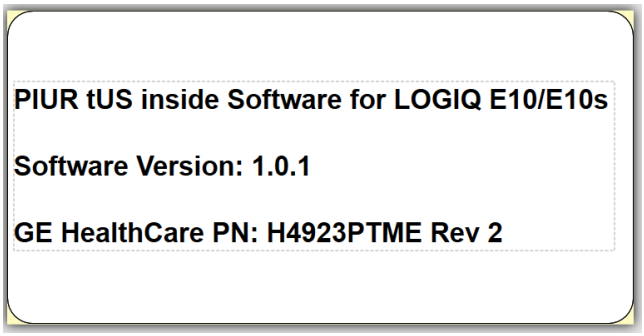


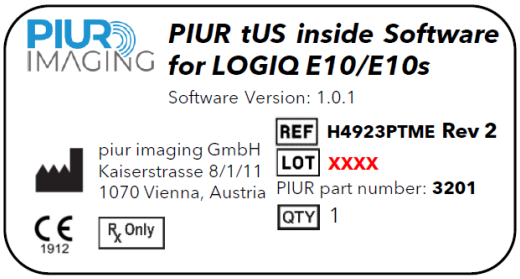
Wireless Charger

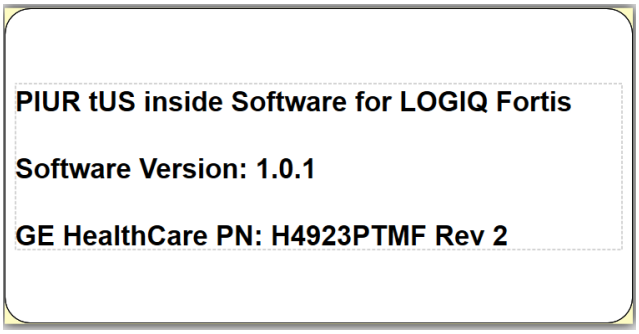
The Label is affixed on the PIUR tUS inside shipping box.

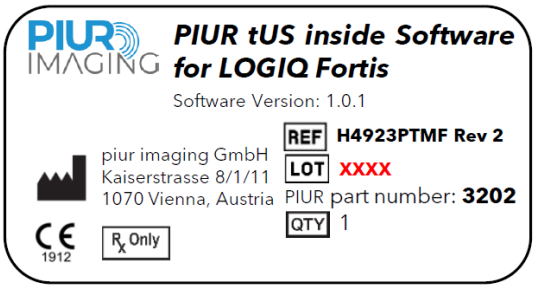


USB Labels



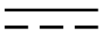






The following additional symbols can be found on the identification label:

Symbol	Description
SN	Serial number
REF	Catalogue number

UDI	UDI Carrier label, containing UDI-DI + UDI-PI parameters, displayed in HRI (human readable interpretation).
	Manufacturer
	CE mark with Notified Body number (ID)
	Operating instructions
	Direct current
	Alternating current (AC)
	The system must not be disposed with normal waste (see chapter 7.5).
	Rx Only means that the device is a prescription device. Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

1.4 Function of this Document

This document provides a detailed description of the PIUR tUS inside and its use within the scope of the application domain it was designed for. It provides instructions for use (IFU) to help the user in the safe and correct operation of the system.

1.5 Intended Use

The PIUR tUS inside serves as a non-invasive, transient and active medical device that is intended to support the user with the examination of thyroid and thyroid nodules, by providing 3D information. 2D ultrasound images, acquired by a compatible third-party ultrasound device and position data, generated by the system-integrated PIUR Sensor, are the basis for 3D image reconstruction. The PIUR tUS inside consists of software and hardware components, including the PIUR Sensor and PIUR Bracket.

The PIUR tUS inside acts as part of the diagnostic chain only and must not be used as a sole source for treatment decisions.

PIUR tUS inside device is not intended for body contact (including skin, mucosal membrane, breached or compromised surfaces, blood path indirect, tissues, bones, dentin, or circulation blood).

1.6 Disclaimer

The manufacturer is not responsible for improper use, failure to comply with the safety notes and non-observation of specifications due to negligence. piur imaging only assumes responsibility for the safety and reliability of the PIUR tUS inside when all changes, enhancements, repairs and other work to the application have been performed by an authorized dealer of piur imaging and certified service person, or piur imaging directly and the User Manual has been observed before and during device operation.

Safety Notice: Do not modify this software application without authorization of the manufacturer.

1.7 General Residual Risk including significant Risks

Considering possible sources of failure, foreseeable and unforeseeable errors of use and after risk mitigation residual risk of this medical product remain. Within the Risk Management process, a total of 84 residual risks + 3 Cybersecurity risks have been identified. There following residual risks are considered as significant:

- Wrong but anatomical correct image

As a diagnostic system the most relevant output of the device is image information. This image information can influence medical decision in terms of therapy, treatment, prevention or further alternative diagnostic information. Caused by various factors the system may display incorrect image information after the image reconstruction. This wrong image information can be caused by erroneous input of image or tracking source or by software or user errors. The wrong image information can either appear as bad image quality or unrealistic image content in terms of anatomical appearance. In both cases the error is obvious to the user. In rare cases the wrong image information can display anatomically reasonable content that cannot be identified as obvious wrong image information and therefore may mislead the user and lead to undesired consequences- in the worst case not getting necessary interventions or surgery or getting unnecessary intervention and surgery. This residual risk affects the patient.

- Infection

Infection is a risk that can occur with any device that comes into contact with the human body, including sensors and brackets. However, it can be easily prevented with proper cleaning techniques. To reduce the risk of infection, it is important to regularly clean and disinfect the sensor and its brackets as recommended in the user manual (chapter 7.3). Failure to do so can lead to the accumulation of bacteria and other harmful microorganisms, which can cause infection and other health problems. By following the correct cleaning procedures, you can help ensure the safety and effectiveness of your device and protect yourself and others from potential health risks.

- Misdiagnosis due to wrong diagnostic output

Misdiagnosis due to wrong diagnosis output is a risk that include two possible situations of incorrect automatic suggestions. The first one is when the doctor accepts incorrect automatic Margin suggestions and the second when doctor accepts incorrect automatic Echogenic foci suggestions. A notification to the user by showing an exclamation mark in the UI for these TI-RADS parameters along with a warning for the user reminding her/him to check these parameters for accuracy, could easily avoid such risk and misdiagnosis.

- Incorrect automatic Margin suggestions

Since margin predictions tend to have a lower accuracy with respect to very rare classes (lobulated / extra-thyroidal extension) the automatic suggestions of echogenic foci proposed to the user might be wrong. Although the system is considered semi-automatic, meaning that the user must accept the proposals or edit if needed, the wrong automatic suggestion could potentially mislead users, particularly those with less clinical experience.

- Incorrect automatic Echogenic foci suggestion

Since echogenic foci predictions tend to have a lower accuracy with respect to very rare classes (peripheral calcifications / punctate echogenic foci), the automatic suggestions of echogenic foci proposed to the user might be wrong. Although the system is considered semi-automatic, meaning that the user must accept the proposals or edit if needed, the wrong automatic suggestion could potentially mislead users, particularly those with less clinical experience.

- Overheating of battery

The battery may overheat due to the lack of ventilation in the protective housing, which is necessary to meet IP rating requirements. Overheating can occur during charging or extended use and must be actively avoided to ensure safe operation.

- Disinfection agent

Disinfection agent used for disinfection can possibly damage sensitive components of medical equipment, such as probe, attachments, screen or cart. Disinfection agents may also harm the device's electronics if not used according to the manufacturer's guidelines.

All residual risks are accepted and considered under the scope of the Risk Management file.

1.7.1 Potential Use Errors Related to User Interface Design and Safety Communication

As information to the user, here are presented the potential use errors (cases) with exact use interface and its characteristics related to safety.

Please ensure that all dropdown fields in the ACR-TIRADS analysis form are fully completed before selecting "Accept". If necessary, use the vertical scrollbar on the right side of the form to view and fill in all required options

When opening a scan, ensure that the desired scan is both selected and correctly opened from the patient list. Please verify that the correct scan (e.g. right vs. left lobe) is displayed before proceeding with the analysis

Please ensure that the correct patient file is selected before starting any analysis.

Please ensure to always pay attention to the screen when using it to not miss system warnings or notifications

Please ensure that the software is displayed in the correct language

See Appendix for further information regarding User Interface Design and Safety Communication.

1.8 Recommendations regarding cybersecurity:

The PIUR tUS inside is embedded in an existing Ultrasound device and therefore follows the cybersecurity recommendations from the ultrasound manufacturer.

The installation process is provided by the US manufacturers (here GE Healthcare) e-delivery system and follows the cybersecurity recommendations from the ultrasound manufacturer.

Backup and restoring is controlled by the US environment and follows the cybersecurity recommendations from the ultrasound manufacturer.

Detection and reporting of cybersecurity vulnerability or incident is communicated to the responsible US manufacturer.

1.9 Contact and Regulatory Information

PIUR tUS inside is classified as non-invasive, transient and active medical device of Class IIa, in accordance with the Medical Device Regulation (EU) 2017/745, Annex VIII.

The conformity of this product according to the general safety and performance requirements of MDR (EU) 2017/745 was proved with the Conformity Assessment Procedure according to Annex IX.

The manufacturer documents that with the CE-Label.

piur imaging GmbH

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1070 Vienna

Austria

CE 1912

2 Safety Regulations

The assembly of medical electrical systems and changes during the actual service life require a check with regard to the requirements set out in EN 60601-1 clause 16. Electrical installations in the room where PIUR tUS inside is used shall comply with the following:

Do not modify this equipment without authorization of the manufacturer.

EN 60601-1 Kap. 7.9.3.1

The system is suitable for use in hospitals and professional healthcare environment except for near active HF surgical equipment and the RF shielded room for magnetic resonance imaging, where the intensity of EM disturbances is high.
EN 60601-1-2 Kap. 5.2.1.1. a)

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

EN 60601-1-2 Kap. 5.2.1.1. c)

Use of components and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
EN 60601-1-2 Kap. 5.2.1.1. e)

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PIUR Sensor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
EN 60601-1-2 Kap. 5.2.1.1. f)

If malfunctions and defects occur.

Occurrence of malfunctions and defects can lead to personal injury or damage to the device.

If malfunctions and defects occur, discontinue the use of the PIUR tUS inside and inform our service team via the above contact details (also chapter 6).

The Sensor contains LED for skin illumination. During the acquisition, this LED should not face the eye.

Do not exchange batteries without authorization of the manufacturer

2.1 User Requirements for Use

- The user has been officially trained by an authorized person in using PIUR tUS inside and is issued with a corresponding certificate.
- The training is provided by authorised service personal and follows the training protocol.
- The training includes system setup, image review, application use, typical errors of use, possible system errors and app closing.
- The system includes turning the sensor on and off, charging, cleaning and an introduction to the LED signals.
- The assistants have carefully read and understood the User Manual.
- The user is required to observe the safety instructions and to adhere to the safety provisions.
- The user has to be a physician skilled in ultrasonic diagnosis.
- Users have knowledge of human anatomy.
- Users have practical experience in the use of ultrasound for medical diagnostics and the fields of applications in which they use PIUR tUS inside.
- Patient should not move during the image acquisition as it could possibly lead to a wrong image data.
- The acquisition should be performed with the recommended speed of 0.5- 2 cm/s.

3 Product Information

3.1 Functionality of the PIUR tUS inside

PIUR tUS inside (Figure 3) is a medical device, which enhances standard ultrasound devices with a three-dimensional tomographic imaging method for a 3D analysis of ultrasound volumes. With PIUR tUS inside, examining physicians can make diagnostic decisions based on standard 2D as well as 3D image data integrated in an ultrasound device environment. This 3D data provides information which previously could have only been generated using other 3D imaging technologies like CT or MRI.

Figure 1: PIUR tUS inside

Three-dimensional ultrasound is already a common method in certain clinical areas. Ultrasound device manufacturers offer methods to create 3D image data. However, the technologies used for 3D image creation vary considerably and all of them have limitations for the imaging of anatomical structures. In order to visualize complete thyroid structures, the system needs to be able to perform non-linear scans measuring up to 20cm.

The PIUR tUS inside runs on a compatible GE Healthcare ultrasound system. The PIUR tUS inside takes as an input a sequence of 2D ultrasound images that are transmitted through a software interface from the ultrasound to the PIUR tUS inside. In addition, the PIUR Sensor must be clipped onto the ultrasound transducer using individually designed brackets. For image acquisition, the user moves the 2D ultrasound transducer perpendicular to the structure to be imaged over the region of interest of the patient's body. An inertial measurement unit (IMU), which is built into the PIUR Sensor, tracks the orientation of the transducer during the scan and sends this information to the ultrasound via Bluetooth (Figure 4). The PIUR tUS inside combines image information and sensor information to generate tomographic 3D ultrasound volumes on which image analysis can be performed.

One important property of this method is the unlimited length of the acquired volume. PIUR tUS inside therefore allows recording and analyzing a complete thyroid lobe.

Figure 2: Acquisition principle

3.2 Clinical Indications

The PIUR tUS inside is used to examine thyroid and thyroid nodule.

3.3 Contraindications

- On patients with open wounds or irritated skin
- During surgery

3.4 Clinical benefits

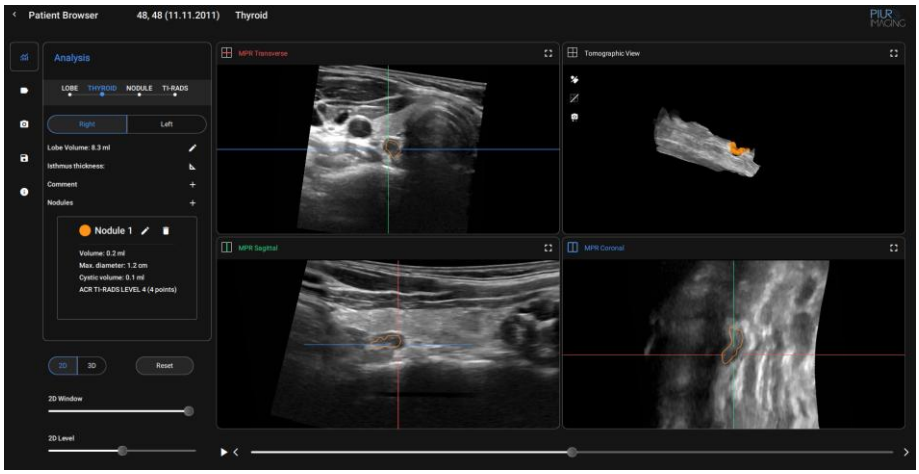
Key Features and benefits of the PIUR tUS inside Thyroid application:

- Accurate 3D volume measurements of thyroid nodules reducing the user dependency of volumetry from 2D US protocols
- Improved monitoring of disease progression over time
- Improved planning of thyroid ablations
- Simplified explanation of disease and treatment decisions to patient through 3D visualizations
- Standardized classification of thyroid nodules

4 System components and Initial Use

4.1 Delivery Package

The deliver package consists of the e-delivered PIUR tUS inside software application installed or installable on the compatible GE Healthcare ultrasound device.



PIUR tUS inside Software

4.2 Components

PIUR tUS inside requires the following components for acquiring tracked scans for 3D reconstruction.

PIUR Bracket
(depending on ultrasound transducer)

REF 34XX

PIUR Sensor

REF 3000

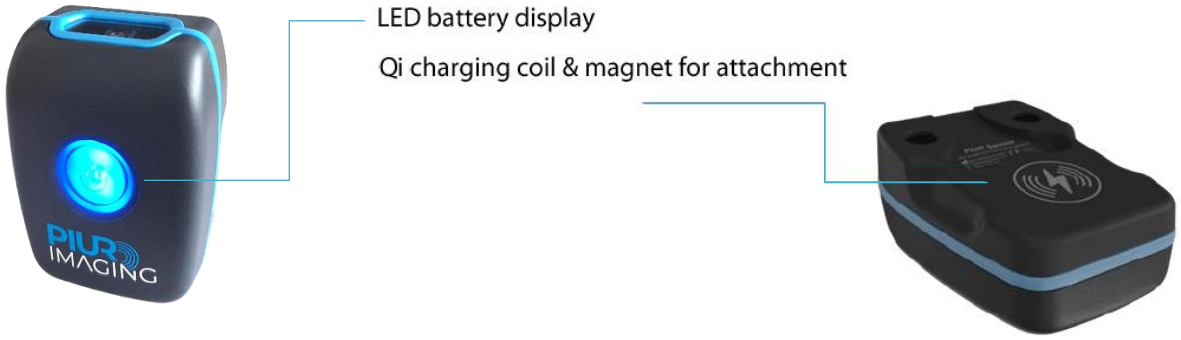
Wireless charger

REF 3300

PIUR Sensor Quick Guide

4.3 Equipment of the main components

Properties



The PIUR Sensor provides information about movement of an ultrasound transducer. it is embedded in a protective housing, which is fixed to the ultrasound transducer through an bracket. The PIUR Sensor can be charged using the provided wireless charger through the Qi 1.2 standard. The Sensor connects to other devices through a Bluetooth interface.

Information:

LED display provides information about the system status.

The PIUR Sensor falls into sleep-mode if battery status is lower than 10% or if sensor has been disconnected for 10 minutes.

Sensor can be re-started manually by pressing the start-button

The PIUR Sensor should be charged immediately after it shows battery status low and before it is not in use for a longer period. EN 60601-1 Kap. 7.9.2.4

Do not connect other Bluetooth devices as headsets or phones with the computer while using the PIUR Sensor

The damage of the sensor window from sharp tools or strong mechanical forces can result in harm to the internal electronics, consequently, lead to the non-usable system

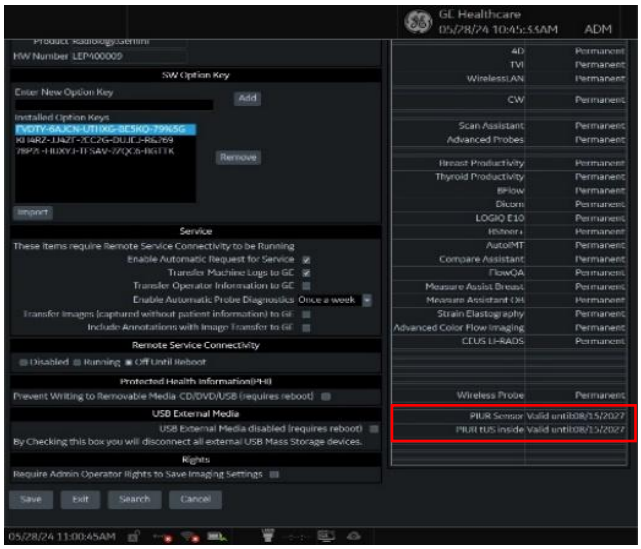
If the user has multiple sensors saved in the software settings, the user must ensure that only one sensor is turned on. The rest of the sensors recommended to be placed on the charging pads

Status	Colour	Position
Sensor is charging	blinking green	On the charging Dock
Sensor fully charged =100%	static green	On the charging Dock
Sensor after turned on & searching for connection (Sensor <15%)	blinking orange	During use
Sensor after successful connection (Sensor <15%)	fast blinking orange	During use
Sensor after turned on & searching for connection (Sensor >=15%)	blinking blue	During use

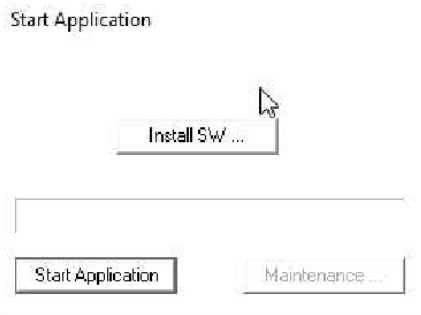
Sensor after successful connection (Sensor >=15%)	static blue	During use
Sensor lost connection	blinking blue	During use
Sensor has error	fast blinking yellow	During use
Sensor startup	static white	During use

4.4 Installation Process

1. Check if there is an available option key for "PIUR tUS inside" on the option key sheet.
2. Enter the option key in the Utility+ -> Admin section.
3. Verify after restart, if the product keys were accepted by verifying the option keys "PIUR Sensor" and "PIUR tUS inside" appearing in the option key status list

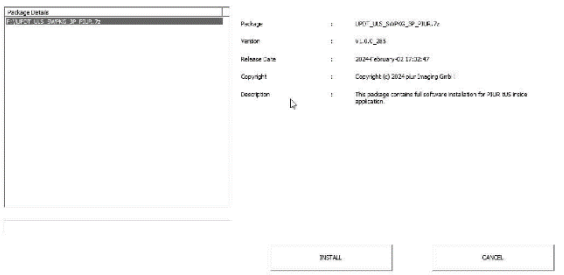


4. Plug-in the USB which contains the software installation files to an available port on the machine.
5. Start the GE ultrasound machine.
6. Execute the installation setup file of software by performing following steps:



In the "Start Application" window, locate and click on the "Install SW" button to initiate the software installation process.

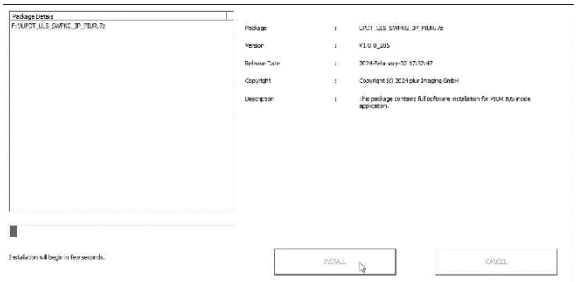
A dialog box labeled "StartLoader" will pop up. Click on "OK" to proceed.



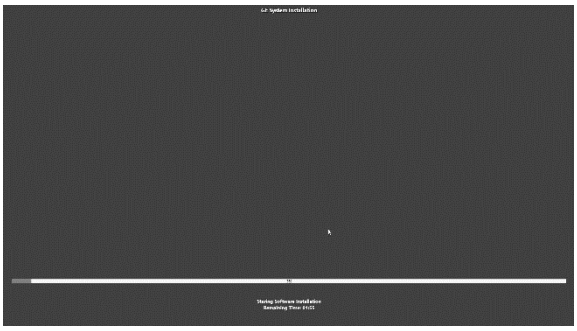
Select the installation package by navigating to

"F:\UPDT_ULS_SWPKG_3P_PIUR.7z"

Once the correct package is selected, click on the "Install" button to begin the installation process.



After clicking "Install", the GE System installation interface will appear, and the installation process will commence shortly.



GE System installation should appear and installation begins

During installation, a logo of Ultrasound model will display at the center of the screen.

Wait until the installation is finished

Once the installation process is finished, you are ready to start working with the software.

4.5 Switching the PIUR Sensor on and off and connect to GE Healthcare US device

1. Turn on the sensor by pressing the Power Button before scanning

2. A blinking blue LED light will signal that the sensor is operational
3. If not in use for several minutes, the sensor will automatically turn off
4. It can be turned off manually by pressing the Power Button, the GE Healthcare device will display a blue and red bar (see the Acquisition Workflow), that the sensor is disconnected
5. Select "SCAN" on the GE device touch panel and swipe on the screen to the left
6. Select "PIUR Sensor" as position sensor type
7. A static blue LED light on the sensor as well as a green signal bar on the GE Healthcare device will (see the Acquisition Workflow) signal that the sensor is connected to the GE Healthcare US device.

Make sure the PIUR Sensor is fully charged before operations.

It is recommended to charge the PIUR Sensor after each use

4.6 Securing the Sensor Bracket to the Probe

Sensor (PIUR) Bracket

Turn the probe as shown in the picture

Hook the PIUR Bracket to the right side of the probe and pull the clip on the Bracket plate over the sensor head until it locks into place with a click. Ensure the correct orientation of the probe.

The bracket must be correctly locked in and secured

Information: Follow the User Manual in the reverse order to disassemble the bracket.

Safety Notice: Use of not certified Brackets

- Only officially Brackets delivered by piur imaging GmbH are allowed to use with the device.

Securing the Sensor Housing on the front Bracket

Place the sensors on the Bracket docking plate. The sensor should be attracted easily by the docking plate.

Make sure the sensor is snapped in properly before continuing with the acquisition workflow.

Information: Follow the User Manual in the reverse order to disassemble the clip.

5 Acquisition Workflow

After completing sections 4.4, 4.5, and 4.6, execute the following steps:

1. Ensure proper connection of the PIUR Sensor to the GE device. The connection will be indicated by:
    a. Green bar on the GE device screen
    b. Constant blue light on the PIUR sensor (described in chapter 4.3 and 7.7)
2. Position the probe, including the PIUR Sensor, on the patient's neck and locate a caudal/cranial position below/above the thyroid gland.
3. After positioning the probe, start the acquisition by pressing the "Mark Cine" button on the GE device.
4. Begin scanning by moving the probe from caudal to cranial / cranial to caudal along the entire side of thyroid. Continue the motion until the probe is positioned cranial above / caudal below the thyroid.
5. Press the "P1" button on the GE device to end the acquisition (see in Tips/Information for the acquisition, Button “P1”).
6. If you want to stop the ongoing scan, press the "Mark Cine" button again. This action will cancel the current acquisition (see in Tips/Information for the acquisition, Button “Mark Cine”).
7. Confirm the tracked loop with the blue cine icon appearing on the cine loop on the left panel (see in Tips/Information for the acquisition, Tracked and untracked loop).
8. Redo process for unscanned thyroid side.
9. After the acquisition was performed, make sure the cine loop marker next to the scan thumbnail on the left side appears in blue, confirming that the scan contains tracking information. If this appears grey, see the following tips/information.

Tips/information for the acquisition:

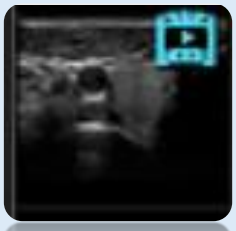
- Move the probe with constant speed, do not stop during sweep for diagnosis
- Make sure the whole thyroid gland is visible during the acquisition time of the probe movement. Change to a larger probe or turn on virtual convex if whole gland is not visible
- Make sure the acquisition includes the whole caudal and cranial end of the thyroid gland
- Be aware that dropping of the scan can occur by clicking the cine mark again, posing a risk of unintentionally discarding the scan.
- Be aware that only the scans with the blue cine loop marker contain the sensor tracking information. If the marker is grey, the sensor information is missing
- Sensor connection is confirmed by the green bar on the screen and the constant blue light on the sensor
- Sensor disconnection can happen due to:
- Entering sleep mode of the sensor (triggered 10 min after not using)
- Sensor battery level is too low
- Sensor is not selected on the GE device as tracking device
- Button Icons Table

Button Mark Cine

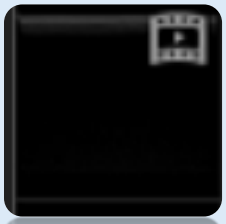
start the acquisition by pressing button

Button P1

stop the acquisition by pressing button



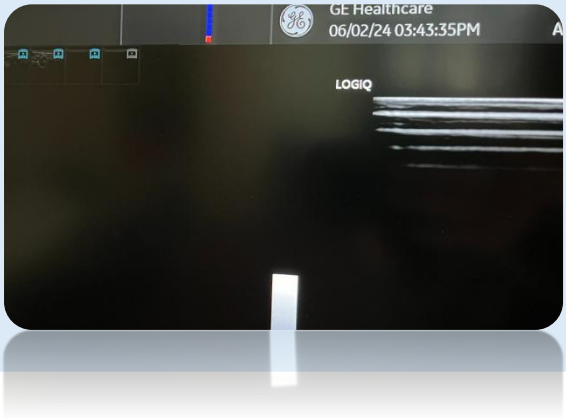
Tracked Loop



Untracked Loop

Green Bar

Confirmation of successful sensor connection



Blue and Red Bar

The sensor is disconnected

6 Review Workflow

6.1 Switching on PIUR tUS inside software

The software application is started by the user interface on the GE Healthcare US device.
From the GE Healthcare US device user interface move to “Utility+” menu. From there you can select the PIUR inside application via touch screen

6.2 User interface overview

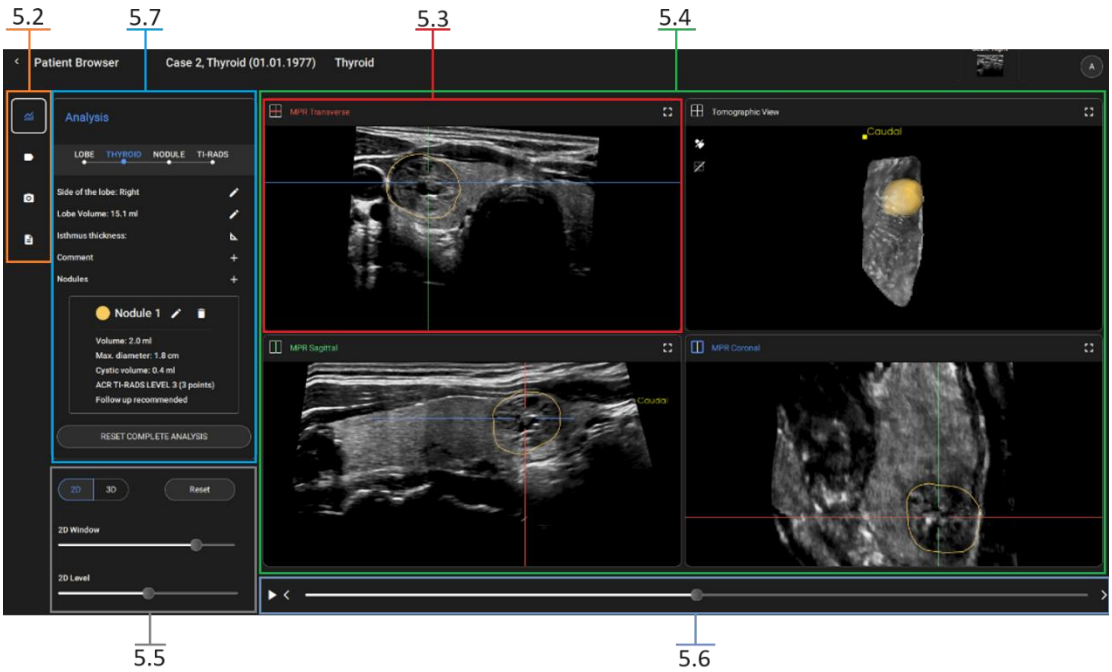


Figure 3: Software main screen overview

5.2 Tool selection

5.3 MPR Transverse

5.4 2D/3D views: MPR Transverse, Tomographic View, MPR Sagittal, MPR Coronal

5.5 Window/Level settings

5.6 MPR Slider

5.7 Thyroid Analysis Workflow

6.3 Tool Selection

	Analyse Lobe and Nodules, see chapter 6.9
	Annotations + Measurements, see chapter 6.10
	Creates a Screenshot of the entire screen and stores it on the GE Healthcare US device.
	Saves all measurements and transfers them to the device database. Warning: Once you saved the analysis, you cannot update or revert this action!
	View Information and Label

6.4 3D view

The 3D view is controlled by:

Icon	Function	Description
	Zoom	Move the cursor to the 3D view. Right click and hold the click. The cursor indicates the current function. Move the trackball down to zoom out, move the trackball up to zoom in.
	Rotate	Move the cursor to the 3D view. Left click and hold the click. The cursor indicates the current function. Move the trackball to rotate the 3D model.
	Move	The Move function is triggered by switching the mode. The mode switches between move and rotate function. After switching the mode, left click and hold the click. The cursor indicates the current function. Move the trackball to move the 3D model.

The 3D View tools:

Icon	Function
	Enables the Visualization of the used transducer for the scan. The transducer follows the actual scan movement.

	Disables the Visualization of the used transducer.
	Enables the MPR planes (Transversal / Sagittal / Coronal) to be shown in the 3D view
	Disables the MPR planes (Transversal / Sagittal / Coronal) to be shown in the 3D view.
	Toggles Visualization. Mode according to default grey Ultrasound image and orange colored Ultrasound image
	Navigating through the image layers in 2D and rotating the volume in 3D is activated.
	Moving the images is activated.

6.5 MPR view

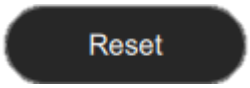
MPR (2D) control units:

Icon	Function	Description
	Scroll	Left Click in the picture in any MPR view. Hold the mouse click. The cursor indicates the function.
	Zoom	Right Click in the picture in any MPR view. Hold the mouse click. The cursor indicates the function.
	Move	The Move function is selected by default. Left click into one MPR view and hold to move the dataset.
	Rotate	Move the cursor on the MPR lines, but away from the center of the cross. The cursor indicates the function switching from move to rotate. Click and hold the Left Mouse pointer to rotate the selected MPR line. After releasing the click, the dataset will stay in the rotated state. Use the reset function to get back to the original view.

6.6 Window / Level settings

The brightness and contrast can be changed by the slider.

Choose between 2D and 3D, to apply on the 2D MPR or 3D view.



Reset the orientation of the MPR and 3D to default. Reset the brightness of the image for 2D and 3D.

6.7 MPR slider

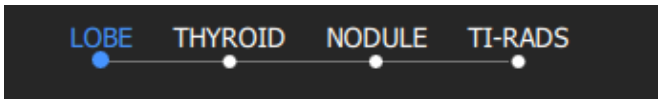
The slider moves along the orientation of the Transversal MPR plane. The bar can be moved with the slider. Or a playback can be started/paused with the button. The left and right arrows can be also used for moving individual slices.

6.8 US device controls

The US device provides embedded user interaction keys to interact with the application.

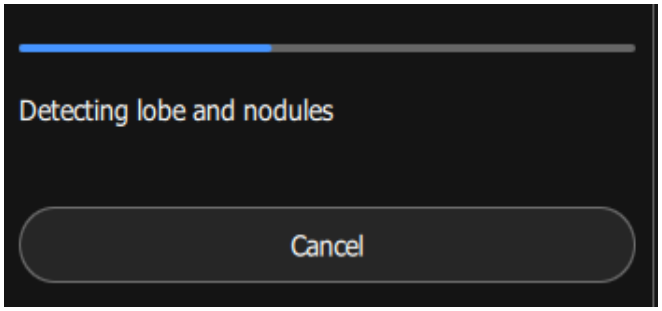
	Controls the scroll bar (refer to 6.7)
	Moves transversal plane
	Moves sagittal plane
	Moves coronal plane
No symbol, labelled “Zoom” on touchpad	Controls Zoom
	Controls window (2D/3D)
	Controls level (2D/3D)

6.9 Thyroid Analysis workflow



Menu Wizard

Press “Start Analysis” to trigger the prediction of the AI Network.



The progress bar gives indication regarding the process. There is also the option to cancel. Pressing cancel stops the analysis and the “Start Analysis” button appears.

The side is automatically detected. By clicking “Right” or “Left” the side can also be selected by the user according to the analysed scan.

The automatic Lobe Volume is displayed.

There are now the options of “correction tool”, “cut tool”, “manual measurement tool”

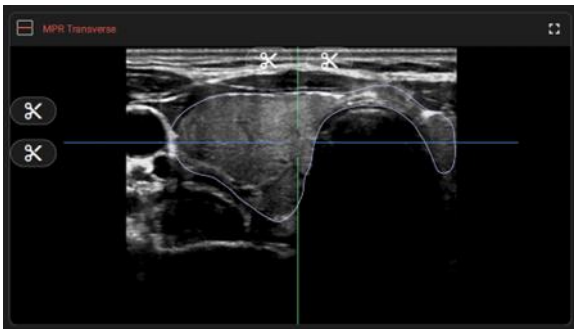
Manual lobe segmentation correction tool.

Here the user can adapt the automatic segmentation manually, by clicking the left and right button as marked in the image.

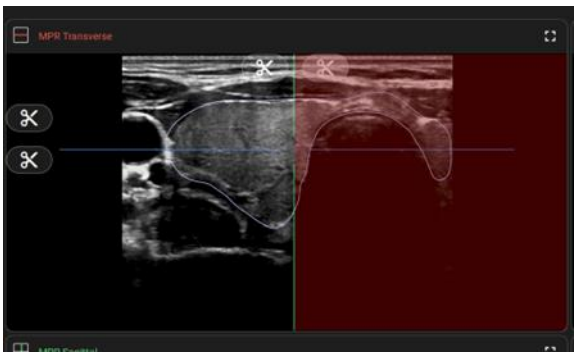
“-” click and hold this button while moving over the parts of the segmentation which should be excluded from the volume segmentation.

"+" click and hold this button while moving over the parts of the segmentation which should be included into the volume segmentation

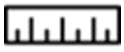
Press the scissor icon, to cut parts of the lobe volume.



Cutting icons are displayed along the planes.



Hover with the mouse over the icon gives a preview of the to cut area.

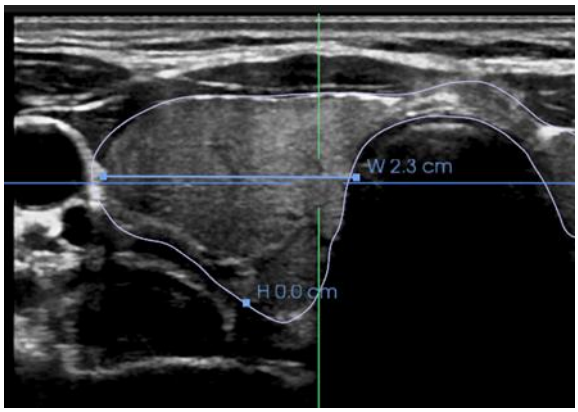


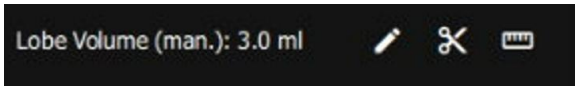
3-line manual measurement tool

(**W**idth, **H**eight and **L**ength).

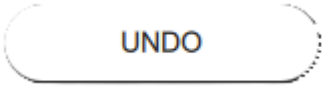
Place the start and end point of each line by clicking in the 2D view.

During the measurement, the respective letter is displayed next to the cursor.





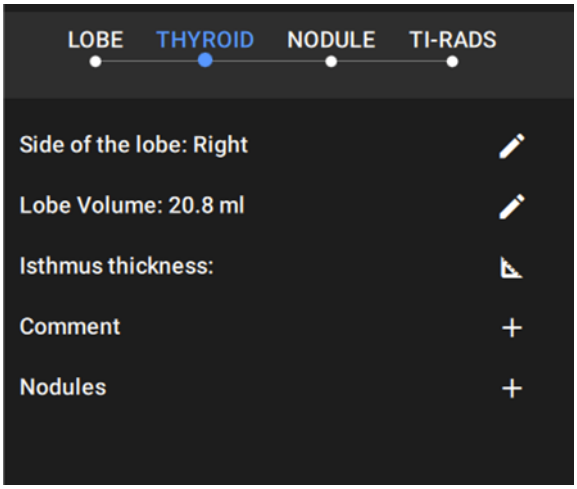
Lobe volume is adapted to the new cut volume.



Jumps one step back, which was performed in the respective tool.

Resets all steps, which were performed in the respective tool.

Accepts and saves the lobe including all editing steps to proceed with the analysis.



The summary of the lobe analysis is displayed including the side and volume of the lobe.

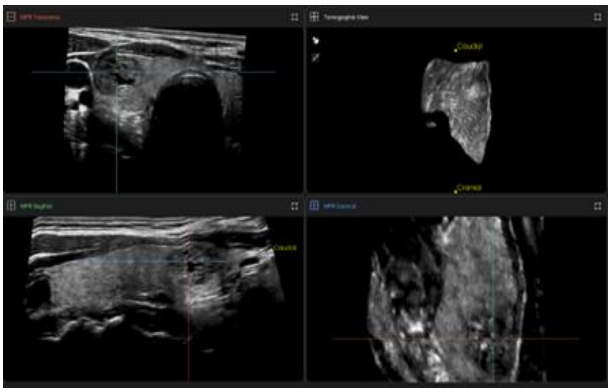
Side/ lobe volume can be edited. Jumps back to the respective menu.

Create a 2-point line measurement in the MPR to measure the Isthmus thickness.

Create a comment by clicking on the plus symbol. Text box opens to add text. Save the comment or discard to return to the previous menu.

Icon of the comment appears after the comment is added

Add a nodule to the analysis by clicking on the plus.



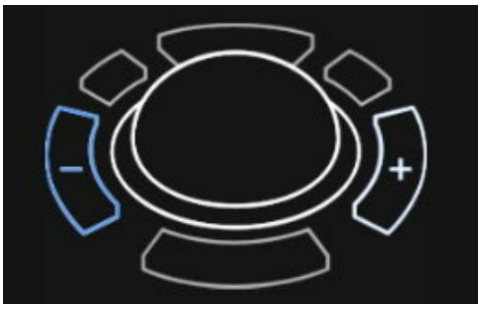
Move the MPRs to the centre of the targeted nodule.

Click in the middle. The detected nodule is shown in the MPR and 3D view.

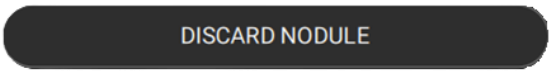
This leads automatically to the manual nodule segmentation correction tool.

Here the user can adapt the automatic segmentation manually, by clicking the left and right button as marked in the image.

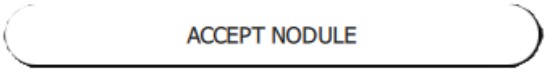
"-" click and hold this button while moving over the parts of the segmentation which should be excluded from the volume segmentation.



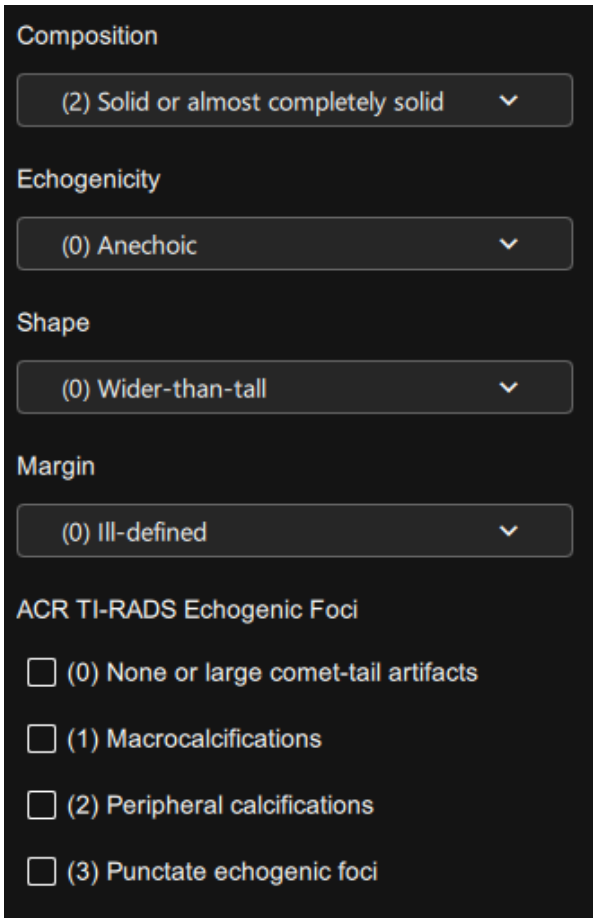
"+" click and hold this button while moving over the parts of the segmentation which should be included into the volume segmentation



Discards the segmentation of the selected nodule including all edits.



Accepts the segmentation of the nodule including all edits. Leads to the next step in the analysis.



The software predicts:

Composition

---

(0) Cystic or almost completely cystic

(0) Spongiform

(1) Mixed cystic and solid

(2) Solid or almost completely solid

Echogenicity

---

(0) Anechoic

(1) Hyperechoic or isoechoic c

(2) Hypoechoic

(3) Very hypoechoic

Shape

---

(0) Wider-than-tall

(3) Taller-than-wide

Margin

---

(0) Ill-defined

(0) Smooth

(2) Lobulated or irregular

(3) Extra-thyroidal extension

ACR TI-RADS Echogenic Foci

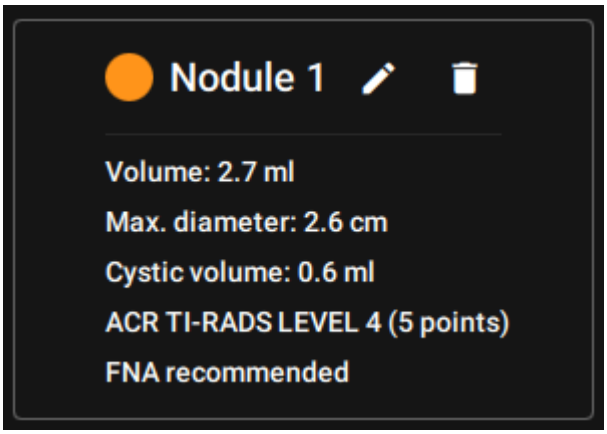
(0) None or large comet-tail artifacts

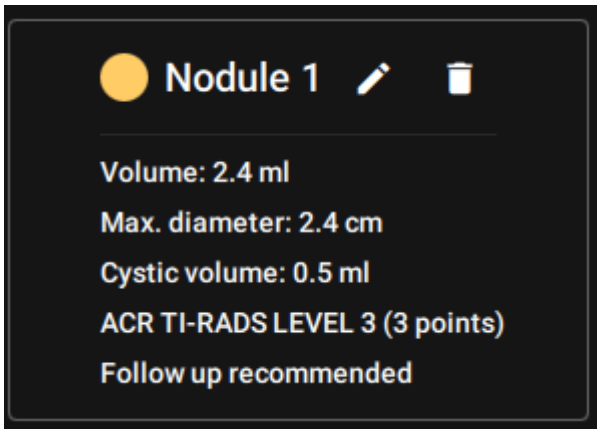
(1) Macrocalcifications

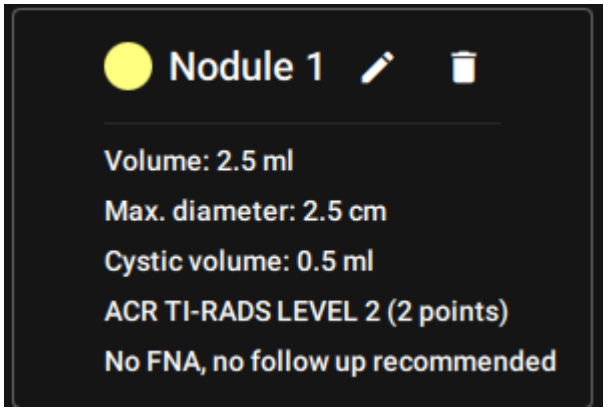
(2) Peripheral calcifications

(3) Punctuate echogenic foci

After reviewing and maybe adjusting, accept the selection.







Overview of the nodule.

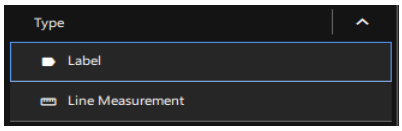
Delete or edit the shown nodule.

The arrow let you jump between multiple nodules.

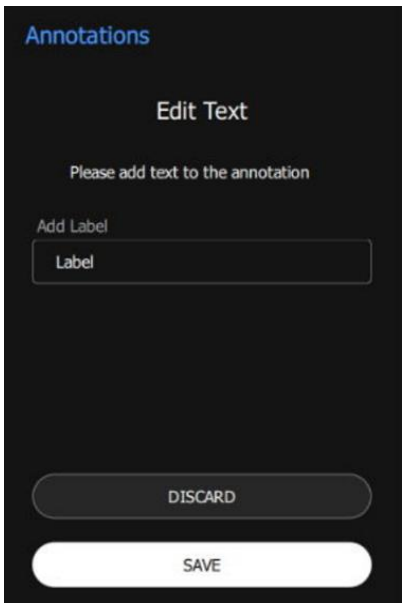
Three recommendations for Nodule are available:

1. FNA recommended
2. Follow up recommended
3. No FNA, no follow up recommended

6.10 Annotations

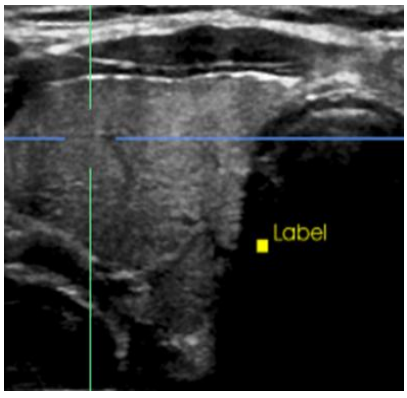


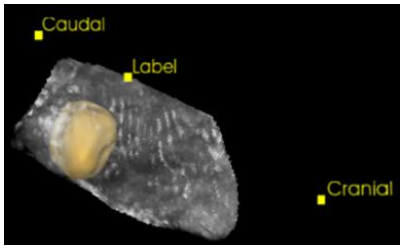
Choose between Label and Line Measurements.



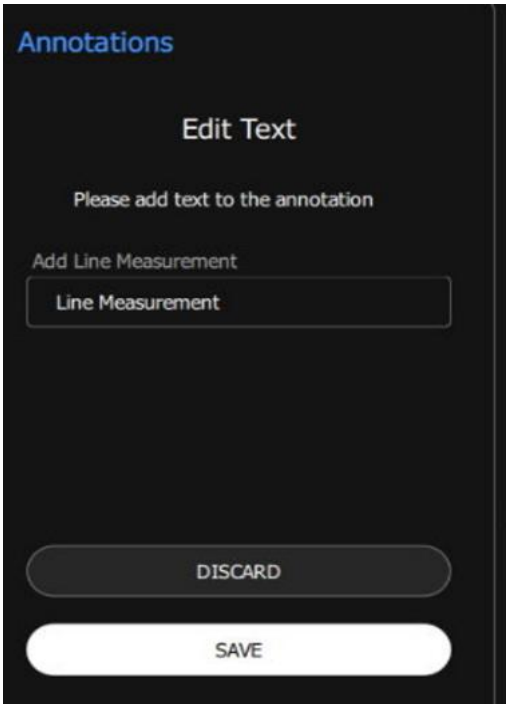
Target the marker in the MPR planes.

Change Label name, discard or save.





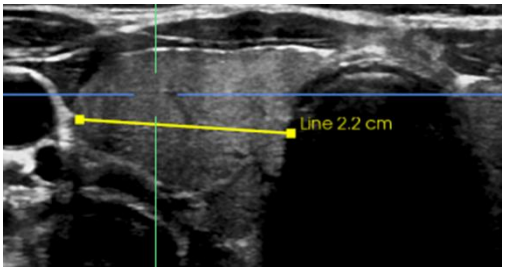
Appearance of the Label in the MPRs and the 3D volume

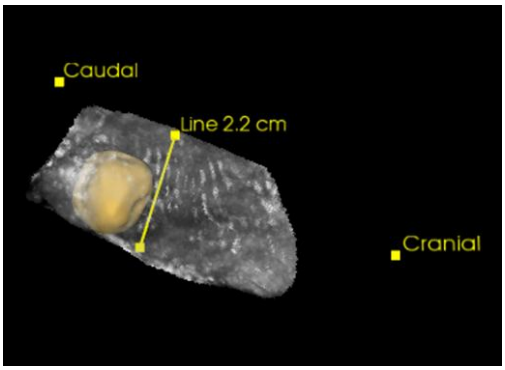


Target the first measurement pint in the MPR plane.

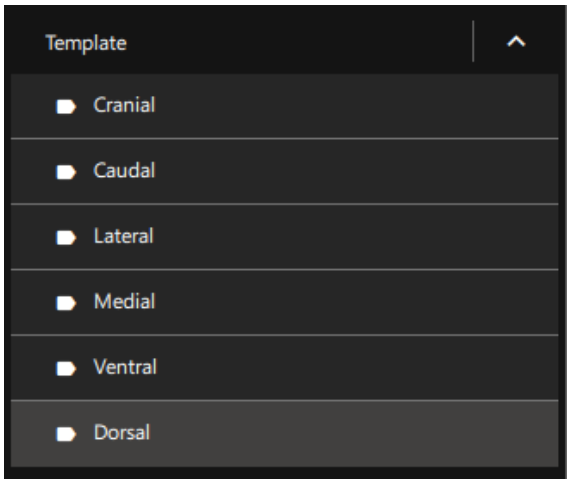
Click the second point to finish the measurement.

The measured value is displayed next to the measurement line.

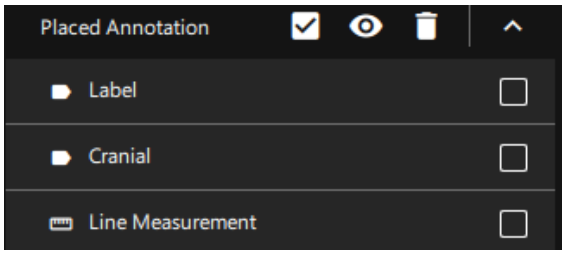




Appearance of Line Measurement in the MPRs and the 3D volume



Select a predefined Label and place it in the MPR plane.



Placed annotations are listed.

Select each annotation by the checkbox.

Select / unselect all checkboxes.

Disable / Enable selected annotations.

Delete selected annotations.

7 Taking out of Operation

7.1 Switching Off and Storing the Device

The application is shut down by the Ultrasound environment.

Ensure you saved all relevant information.

7.2 Charging and Storing the Device

Charging of PIUR Sensor is done wirelessly.

1. Place PIUR Sensor on a charging pad.
2. A charging label printed on the bottom of PIUR Sensor must align with the center of the charging pad.

Figure 4: PIUR Sensor on a charging pad

LED feedback:

Illumination	**Information about system status**
▪ Blinking green	On the charging pad, battery is charging
▪ Static green	On the charging pad, battery is fully charged
▪ Static blue	Off the charger, Sensor is connected and charged
▪ Blinking blue	Off the charger, Sensor is not connected and charged
▪ Static yellow	Off the charger, Sensor is connected and less than 15% charged
▪ Blinking yellow	Off the charger, Sensor is not connected and less than 15% charged

7.3 Disinfecting and Cleaning

7.3.1 Cleaning and Disinfecting the PIUR Sensor

The PIUR Sensor must be cleaned before and after each use in accordance with the applicable disinfection and cleaning rules.

- To ensure optimal hygiene and performance, the PIUR Sensor **must be cleaned after each use**. For added safety, **cleaning before use is also recommended**.

1. Remove the sensor housing from the bracket plate by levering it diagonally downwards with one hand.
2. Carefully remove all soiling and residues from the sensor housing, using a soft damp cloth if necessary.
3. Wipe the sensor surface with CaviWipesTM.
4. Let the sensor dry for about 2 minutes.

Safety Notice

Never submerge the PIUR sensor in disinfectant or any other liquid. Submerging of the component results in a loss of warranty and may cause damage to the system and endanger the patient. If these components are accidentally submerged into any substance, please contact the manufacturer.

7.3.2 Removing and Cleaning the Bracket

Clean and disinfect the after every patient examination, as follows:

1. Release the bracket from the anchoring by applying slight pressure to the bracket plate and remove it from the ultrasound probe.
2. Wipe bracket, with CaviWipesTM.
3. Let the bracket dry for about 2 minutes.

Safety Notice

Never sterilize (e.g. autoclave) the components of the system. Sterilization of any of these components results in a loss of warranty and can cause damage to the system and endanger the patient. If these components are accidentally sterilized, please contact the manufacturer.

To ensure optimal hygiene, the PIUR Bracket **must be cleaned after each use**. For added safety, **cleaning before use is also recommended.**

Before starting cleaning and disinfection, please note the following:

- None of the (electrical) components shall have any visible damage; otherwise, water or cleaning/disinfection solution could penetrate. This could cause malfunctions or damage to the electrical components.
- Do not apply diving cleaning or disinfection.

Strictly follow the application instructions specified on the detergent used, disinfectant!

In accordance with the statutory hygiene regulations for the prevention of infections and the requirements for the treatment of medical devices, a careful and effective cleaning and disinfection must be carried out after each use.

If coarse impurities are visible, they must be removed with an appropriate cleaner (or disinfectant cleaner) before disinfection.

Appropriate means of disinfection must be used, the material compatibility of which has been demonstrated:

Cleaning Agent	Active Ingredient	Dry time
CapiWipes™ (Disinfectant Wipes)	Quaternary ammonium germicidal detergent solution	2 Minutes

WARNING: Do not use any liquid or aerosol cleaner, only determined cleaning solution (agent) specified above.

7.4 Disposing of PIUR tUS inside software

To uninstall the PIUR tUS inside software from the device please contact Service. Contact data can be found in section 8.1.

7.5 Disposing of PIUR Sensor

The PIUR Sensor must be disposed in accordance with the national guidelines for electronic scrap. Alternatively, the device can be sent back to the manufacturer for disposal.

8 Service and Maintenance

8.1 Contact

service@piurimaging.com

Hotline: +43-12 650 16 8

Please write down the software version before contacting our service team. You can find the software version number in the Info screen of PIUR tUS inside on the information icon (see chapter 1.3.1).

8.2 Maintenance Interval

PIUR tUS inside does not require maintenance.

Information: Batteries Cycle Life at room temperature may drop to 80% of minimum capacity after 500 cycles or 2 years (depending on charging).

PIUR Sensor will anyway indicate when batteries are depleted.

8.3 Software Update

The user is not permitted to carry out software updates. Software updates are performed by trained service personnel or provided through the GE Healthcare app store.

8.4 Procedure in Case of Faults and Defects

Safety Notice: If malfunctions and defects occur.

Occurrence of malfunctions and defects can lead to personal injury or damage to the device.

- If malfunctions and defects occur, discontinue the use of the PIUR tUS inside and inform our service team via the above contact details.

9 Technical Data

9.1 Compatibility

US Manufacturer	US Model	PIUR inside Software version	GE device software version	Probe Model	Bracket Model	Display Resolution
GE	LOGIQ E10	v1.0, v1.0.1, v1.1	R4.1	L3-12 ML6-15 ML4-20	Standard G3 Bracket	1552x970
GE	LOGIQ E10s	v1.0, v1.0.1, v1.1	R4.1	L3-12 ML6-15 ML4-20	Standard G3 Bracket	1552x970
GE	LOGIQ Fortis	v1.0, v1.0.1, v1.1	R4.1	L3-12 ML6-15	Standard G3 Bracket	1552x970

The minimum hardware requirements for PIUR tUS inside and criteria that must be met for compatibility:

- GE Ultrasound API environment
- Image framerate > 25 fps possible
- Windows 10 64-bit operating system
- Nvidia Graphics Card 4GB GPU memory (with CUDA)
- 16GB RAM
- Bluetooth 4.0 or higher

9.2 Technical Data

Parameter	PIUR Sensor
Voltage	3,7 VDC (Lithium Polymer)
Power input	~ 0,15W
Dimensions	41,8x56,2x25,3 mm
Mass (without packaging)	40 g
Lifetime	2 years (due to Battery depletion) *NOTE: Battery should be replaced after 2 years preventively, not to affect the lifetime of main product, i.e. to maintain safety and performance of the medical device!*
Storage and transport condition	• Temperature: -10 °C to +60 °C • Relative humidity: 10 % – 90 % (no outside storage) • Atmospheric pressure: 50 kPa to 106 kPa (EN 60601-1-2:2015 Annex A 7.9.3.1) • Store at 0–30°C in a dry, dark place; Use or recharge within 3 months
Recommended operating conditions	• Temperature: +10 °C to +30 °C • Relative Humidity: 30 % to 75 % (EN 60601-1-2:2015 Annex A 7.9.3.1) • Atmospheric pressure: 70kPa to 106 kPa (EN 60601-1-2:2015 Annex A 7.9.3.1)
Recommended operating altitude	Maximal 2000 m

9.3 Measurement Function

Safety Notice: Accurate measurements can only be performed in the "Performance"-Domain of Tracking Sensor (i.e. in the same room as the system)

In case of leaving the "Performance"-Domain during a measurement, a warning will appear.

The accuracy of PIUR tUS inside:

- The PIUR tUS inside, G3 sensor showed a smaller relative volumetric range of error (–21.24% to +10.38%) compared to 2D ultrasound, B-mode (–34.72% to +25.79%), where the range of error corresponds to the region containing 95% of measurements.

Aim:

The objective of this bench study was to compare the volumetric accuracy of PIUR tUS inside (G3 sensor) with 2D B-Mode ultrasound using phantoms with known ground-truth volumes.

Methods:

The study was conducted using 6 agar phantoms representing thyroid nodules, mounted on trachea-shaped pedestals. The phantoms had volumes of 4.14 mL, 4.44 mL, 5.62 mL, 4.35 mL, 4.73 mL, and 6.70 mL. Ground truth (GT) volumes were established by the water-displacement method and verified by 3D scan, CT, and a 31-day repeat, confirming stability. Each of the six phantoms was measured using multiple imaging modalities, including the investigational method PIUR tUS (G3 sensor) and the reference standard 2D ultrasound. Measurements were performed independently by two experts, resulting in a total of 12 measurements per modality.

The primary endpoint was to measure the relative volumetric error (%). The results were summarized as the 95% relative interval error.

Since the sample size is small (2 readers x 6 phantoms), normality cannot be assumed. Therefore, the non-parametric Wilcoxon signed-rank test was applied for significance testing at a significance level of 0.05. The following hypotheses were evaluated:

- Whether there is a significant difference between PIUR tUS (G3 sensor) and the ground truth. This test assessed whether the median of relative volumetric error calculated between PIUR tUS (G3 sensor) and ground truth differs from 0.
- Whether there is a significant difference between 2D B-Mode ultrasound and the ground truth. This test assessed whether the median of relative volumetric error calculated between 2D B-Mode Ultrasound and ground truth differs from 0.
- Whether the median difference between PIUR tUS (G3 sensor) and the ground truth differs significantly from the median difference between 2D B-Mode ultrasound and the ground truth.

Results:

For PIUR tUS inside, the 95% of relative errors lay within interval of -21.24% to +10.38%. For 2D B-mode ultrasound the interval was -34.72% to +25.79%. It was demonstrated that relative error interval for PIUR tUS inside is narrower than for 2D Ultrasound, indicating higher accuracy. The relative errors were shown on Bland-Altman plot, on Figure 5.

The median relative volumetric error between PIUR tUS (G3 sensor) and the ground truth was –3.37%. The Wilcoxon signed-rank test yielded a p-value greater than 0.05, indicating no statistically significant difference between the PIUR tUS (G3 sensor) and the ground truth.

For 2D B-Mode ultrasound, the median relative volumetric error was –3.73%. The Wilcoxon signed-rank test resulted in a p-value greater than 0.05, also indicating no statistically significant difference from the ground truth.

Finally, the median difference between PIUR tUS (G3 sensor) and the ground truth compared to the median difference between 2D B-Mode ultrasound and the ground truth was 0.275%. The Wilcoxon signed-rank test resulted in a p-value of 0.91. This result suggests that there was no significant difference between the two methods.

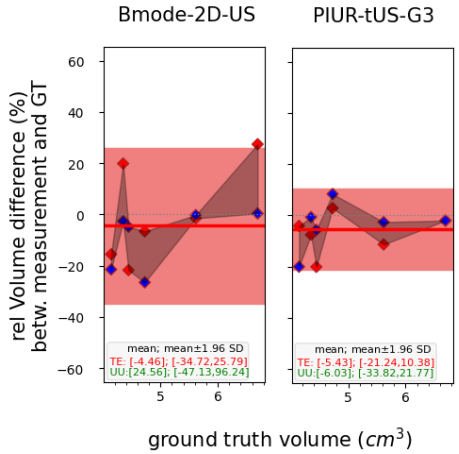


Figure 5: Relative volumetric error demonstrating difference between Ground Truth and two imaging modalities

Conclusion:

Across these phantoms, PIUR tUS inside (G3 sensor) showed a narrower error band than 2D B-mode, indicating better volumetric accuracy compared to the gold standard 2D ultrasound.

9.4 Classification

	PIUR Sensor
Protection class	Internally powered device
IP classification	IPx5

9.5 Electromagnetic compatibility (EMC)

The PIUR Sensor fulfils the requirements of the standards: EN 60601-1-2:2015,

- EN 60601-1-2:2015 + A1:2021
- EN 60601-2-37:2016
- EN 301 489-1 V2.2.3 (2019-11)
- DRAFT EN 301 489-17 V3.2.5 (2022-08)

The PIUR Sensor is classified according to CISPR 11 as group 1, class B.

Under EN 60601-1-2, the DUT is classified into group 1, class B, according to CISPR 11 and into class B according to CISPR 32.

Under ETSI EN 301 489-1, the DUT is classified into class B according to CISPR 32.

	PIUR Sensor
Frequency band of reception	2,4 GHz ISM frequency band EN 60601-1-2:2015 5.2.2.3
Bandwidth of the receiving section	max. 1 Mbit/s
Frequency band of transmission	2,4 GHz ISM frequency band
Type and frequency characteristics of the modulation	IEEE 802.15.1 EN 60601-1-2:2015 5.2.2.4
Effective radiated power	5 dBm EN 60601-1-2:2015 5.2.2.4

Use Environment

The device is intended to be used in a standard clinical or hospital environment where diagnostic ultrasound examinations are being performed. This setup usually includes an ultrasound system, and potentially additional medical equipment. The system is not intended to be used in operating rooms, or in rooms with heavy imaging devices that could cause strong EM disturbances, such as an MRI.

Do not operate device in an environment with known increased EM disturbances. Do not use devices which intentionally transmit RF Signals (cellular phones, transceivers, or radio-controlled products), other than those supplied by PIUR, in the vicinity of the equipment, as it may cause performance outside the published specifications. Keep the power to these type devices turned off when near this equipment.

Please also see environmental conditions Chapter 9.2

Expected functions and performance

All types of electronic equipment may characteristically cause electromagnetic interference with other equipment, either transmitted through air or connecting cables. The term EMC (Electromagnetic Compatibility) indicates the capability of equipment to curb electromagnetic influence from other equipment and at the same time does not affect other equipment with similar electromagnetic radiation from itself.

Proper installation following the user manual is required in order to achieve the full EMC performance of the product. The product must be installed as stipulated in 4.4, Connection with the Ultrasound Device.

The PIUR Sensor should connect to the workstation though a Bluetooth signal and should remain connected without interruptions.

In case of issues related to EMC, please call your service personnel.

Immunity and Emission Testing

The device has successfully passed the following emission measurements according to EMC Test Plan and EN 60601-1-2:

- Norm Ref.: CISPR 11 - Radiated emissions 30 MHz to 1000 MHz

The device has successfully passed the following emission measurements according to EMC Test Plan and ETSI EN 301 489-1:

- Norm Ref.: EN 55032 class B - Radiated emissions 30 MHz to 1000 MHz

The device has successfully passed the following immunity tests according to EMC Test Plan, EN 60601-1-2 and EN 60601-2-37:

- Norm Ref.: IEC 61000-4-2 - Electrostatic discharge immunity test
- Norm Ref.: IEC 61000-4-3 - Radio-frequency electromagnetic fields immunity test
- Norm Ref.: IEC 61000-4-3 - Proximity field from RF wireless communications equipment immunity test
- Norm Ref.: IEC 61000-4-8 - Power frequency magnetic fields immunity test

The device has successfully passed the following immunity tests according to EMC Test Plan and ETSI EN 301 489-1:

- Norm Ref.: IEC 61000-4-2 - Electrostatic discharge immunity test
- Norm Ref.: IEC 61000-4-3 - Radio-frequency electromagnetic fields immunity test

Summary Table Electromagnetic Emissions and Immunity Declarations

Emissions Test	Compliance Level
RF Emissions, CISPR 11	Group 1, Class B Compliant Radiated emissions 30 MHz to 1000 MHz
IEC 61000-4-2 Electrostatic discharge immunity test	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge
IEC 61000-4-3 Radio-frequency electromagnetic fields immunity test	10 V/m; 80 MHz – 2,7 GHz; 1 kHz / 80 % AM
IEC 61000-4-3 Proximity field from RF wireless communications equipment immunity test	Compliant
IEC 61000-4-8 Power frequency magnetic fields immunity test	30 A/m, 50 Hz / 60 Hz

Unexpected Disturbances and Malfunctions

EM disturbances as normally present in the defined use environment have no impact on the performance and functionality of the device. However, strong, unexpected EM disturbances at frequencies or intensities outside of the tested values might affect the performance of the device as follows:

- Sensor malfunctions and does not turn on
- Bluetooth connection of sensor might not be possible

10. Appendix

10.1 Usability and Safety-Related Design Requirements

The following requirements have been implemented to ensure safe and effective use of the device in accordance with ISO 24971:2020. These requirements address key human factors and usability considerations and are intended to support risk mitigation related to user interaction.

User Interface Design Minimizes Use Errors

The user interface is designed to reduce the likelihood of use errors. Particular attention has been paid to the layout of controls, indicators, and menus; the visibility of warnings; the audibility of alarms (IEC 60601-1-8); and ergonomic considerations. The design follows IEC 62366-1 guidelines to ensure intuitive and error-tolerant operation.

Consideration of Environmental Distractions

The design accounts for the possibility of use errors caused by environmental distractions, such as noise, interruptions, or repetitive tasks. The system remains operable and safe under realistic environmental conditions typically encountered in the intended use setting.

Clear and Accessible Display of Information

Displayed information is designed for clarity and visibility across all intended user populations and environments. Considerations include lighting conditions, display orientation, appropriate use of color and units, and emphasis on critical values to prevent misinterpretation.

Control Interface Minimizes Confusion and Errors

Control elements are structured to prevent slips, confusion, and operational mistakes. Design considerations include spacing, grouping, control labeling, visibility, feedback, directionality, and the ability to reverse actions where appropriate.

Provision of Information for Safe Use

All safety-relevant information is provided in a clear and accessible format. This includes instructions for installation, operation, and training requirements. Information may be directed at different user groups (e.g., end users, healthcare professionals, technicians) depending on the context of use.

Prevention of Incorrect Use of Connectors and Supplies

The design ensures that connectors and supplies cannot be incorrectly attached or confused with non-compatible components. Risks such as over- or under-tightening, incorrect fit due to similarity, or inadequate feedback during connection are minimized by mechanical and visual safeguards.